

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 09/720,096 Confirmation No.: 6906
Applicants : Dan Nilsson, *et al.*
Filed : February 1, 2001
Title : METHOD OF PREVENTING BACTERIOPHAGE INFECTION OF
BACTERIAL CULTURES
TC/Art Unit : 1656
Examiner: : David J. Steadman, Ph.D.

Docket No. : 54337.000009
Customer No. : **21967**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF SUBSTANCE OF EXAMINER INTERVIEW

Sir:

This communication is responsive to the Interview Summary Record mailed July 31, 2009.

Applicants appreciate the in-person interview granted by Examiner David J Steadman, Ph.D., on July 29, 2009. During the interview, the claim amendments filed July 1, 2009 were discussed. Applicants presented arguments that the amendments overcome the previously stated written description rejections. Examiner Steadman perused the amended claims during the meeting and indicated that there was no immediately apparent basis for maintaining the written description rejections. However, he noted that he would need to make a formal determination when he took the case up for action within the next month or two and noted that this would be governed by the updated Office guidelines for written description examination. Applicants suggested that Example 16 of the Written Description Training Materials, rev. 1, March 25, 2008

(“Process Claim Where Novelty Resides in the Process Steps”) is closely analogous to the present claims and provides a rationale for finding sufficient written description for the present claims.

Applicants maintained that no prior art reference teaches or suggests the use of the recited auxotrophic mutants for fermentation of milk products as claimed. In response thereto the Examiner made reference to specific teachings in Dickely *et al.*, *Isolation of Lactococcus lactis nonsense suppressors and construction of a food-grade cloning vector*, Mol Microbiol. 1995 Mar;15(5):839-47 (“Dickely *et al.*”) was discussed. See IDS submitted December 21, 2000. In response Applicants noted that a patent reference which is very analogous in its relevant teachings to this reference (Dickely US Patent 5,691,185) had been cited earlier against the claims during prosecution in an obviousness rejection and withdrawn..

In fact Dickely teaches against the use of the subject mutants in a fermentation process as claimed. Rather it was explained that the Dickely reference. teaches that a purine auxotroph mutant is “unable to grow in milk,” (which would teach against the claimed milk fermentation process) and primarily relates to the use of a suppressor of this mutation as a selectable marker for maintaining a desired plasmid (e.g., as an alternative to the use of antibiotics).

Applicants also noted that that claims of broader scope than those currently pending stand allowed in the corresponding EP patent application no. EP99931021 despite citation of Dickely *et al.* in “third-party observations.”

More particularly, in response to the Examiner’s referral to the purine auxotrophic bacterial strain DN209 and plasmid-bearing isolates DN209 (pFG1) and DN209 (pFG2) mentioned in Dickely *et al.* Applicants emphasized that the reference clearly states that DN209 is “unable to grow in milk” (pg. 842, right column) due to a nonsense mutation in a purine biosynthesis gene, and accordingly does not teach or suggest their use in a method of fermenting milk under conditions resulting in acidification.

It was also explained that plasmids pFG1 and pFG2 contain a complementing suppressor tRNA (*supB*; see Table 3) and, accordingly, **strains DN209 (pFG1) and DN209 (pFG2) are not purine auxotrophs.** Thus, in contradistinction to the claimed invention Dickely *et al.* does not teach or suggest any use of a purine auxotrophic strain for fermentation of milk or milk products;

moreover, the reference teaches away from the present claims because the purine auxotrophs are said to be “unable to grow in milk” unless the purine auxotrophy has been complemented.

Applicants also noted (as mentioned above) that an obviousness rejection had previously been made and withdrawn over a similar primary reference, Dickely US Patent 5,691,185 (“Dickely ‘185”), entitled *Lactic acid bacterial suppressor mutants and their use as selective markers and as means of containment in lactic acid bacteria*. Dickely ‘185 appears to be the patent counterpart of the non-patent Dickely *et al.* reference and discloses essentially the same strains, plasmids, and uses thereof that were discussed at the interview, namely: the aforementioned strains DN209 and plasmids pFG1 and pFG2, the inability of a purine auxotroph to grow in milk, and the use of these plasmids to complement the purine auxotrophy and permit growth in milk while selecting for plasmid retention. The rejection over Dickely ‘185 was withdrawn in the Office Action mailed January 23, 2003, as follows:


All rejections under 35 USC 103(a) are withdrawn for the following reasons. While Dickely teaches purine auxotrophs of *L. lactis* and that milk contains insufficient amounts of purine or pyrimidine nucleotides to support the growth of purine or pyrimidine auxotrophs of lactic acid bacteria, the examiner can find no teaching or suggestion in the prior art of record that such *L. lactis* purine auxotrophs would be able to acidify milk, even if the milk were contaminated with phage. Furthermore, the examiner can find no teaching or suggestion to motivate one of ordinary skill in the art to use the *L. lactis* purine auxotroph of Dickely for acidification of milk.

Applicants are of the view that the rationale for withdrawing Dickely ‘185 is equally applicable to the claims as presently amended. Accordingly, Applicants respectfully submit that a rejection over either Dickely reference would not be warranted.

In conclusion, Applicants respectfully submit that the application in condition for allowance. The Examiner is invited to contact the undersigned (direct line (703) 714-7645) to resolve any additional issues that may arise.

No fees are believed to be due for this Statement of Substance as it is timely filed. However, the Commissioner is hereby authorized to charge payment of any fees required under 37 C.F.R. § 1.16 and § 1.17 associated with this communication or credit any overpayment to the deposit account of Hunton & Williams, **Deposit Account Number 50-0206**.

Respectfully submitted,
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